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No. 85-664

In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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As we established in our opening brief, since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, nearly 50 years ago, the Food and Drug Administration (FDA) has consistently construed the Act as allowing the agency to regulate the presence in food of necessary or unavoidable added contaminants, such as aflatoxin in corn, either by exercising its broad prosecutorial discretion to bring individual enforcement actions pursuant to Section 402(a)(1), 21 U.S.C. 342(a)(1), or by adopting regulations ("tolerances") via formal rulemaking pursuant to Sections 402(a)(2)(A) and 701(e), 21 U.S.C. 342(a)(2)(A) and 371(e). The agency's construction of these provisions is fully consistent with their overall structure and legislative history, with the role that they play in the enforcement process, and with this Court's understanding of their operation. See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161, 166-167 (1958). The FDA's longstanding regulatory practice has not compromised the public health or resulted in inadequate enforcement of the food adulteration provisions of the statute, and it has enabled the agency to allocate its scarce resources to matters of more urgent public concern. Congress has also been made aware of the agency's construction of the FDCA on several occasions during this

period and has neither criticized the agency nor required it to alter its regulatory practice. On the contrary, Congress has modified other sections of the FDCA in express reliance on the FDA's views. For these reasons, and because the court of appeals failed to give any deference to the views of the expert agency responsible for administering a complex regulatory scheme (see, *e.g.*, *United States* v. *Riverside Bayview Homes, Inc.*, No. 84-701 (Dec. 4, 1985), slip op. 9-10, 17; *Chemical Manufacturers Ass'n* v. *NRDC*, No. 83-1013 (Feb. 27, 1985), slip op. 8), it is our submission that the court of appeals misconstrued Section 406 of the FDCA.

1. For the most part, respondents' answer (Br. 18-20) to our argument is simply that the term "shall" in Section 406 should be given its literal, dictionary meaning and that Section 406 therefore requires the FDA to adopt tolerances for every necessary or unavoidable added contaminant. That argument fails for several reasons.

a. First, as we explained in our opening brief (at 24-25), the construction of Section 406 adopted by the court of appeals renders the general food adulteration standard in Section 402(a)(1) wholly superfluous for added contaminants such as aflatoxin, even though the text of Section 402(a)(1) shows that it applies to such added substances.[1] Respondents attempt to

[1] Nor is the court of appeals' construction of Section 406 compelled by the text of that section when it is read as a whole. Respondents agree (Br. 18) that the phrase "to such extent as [the Commissioner] finds necessary for the protection of public health" would authorize, rather than require, the FDA to adopt tolerances if that phrase were adjacent to the verb "shall." However, the eight words separating these terms in Section 406 can scarcely be taken as manifesting a congressional intent wholly to preclude any effect of the former upon the latter. The origin of the "to such extent" clause makes this point. That clause was included in the bill that became the FDCA when the text of the bill provided that the FDA was "authorized" to issue tolerances. See Amicus Nat'l Food Processors Ass'n Br. App. 5a comment. The "to such extent" clause was thus clearly intended to guide the FDA's decision *whether* to set a tolerance, not the decision what particular tolerance level should be set.

Moreover, respondents' claim (Br. 30 n.7) that the "to such extent" clause "was included to describe the standard for setting tolerances" is inconsistent with the final sentence of Section 406, which explicity prescribes the factors to be taken into account in determining the quantity of the substance to be tolerated. Only the "to such extent" clause served or could serve to established a standard for deciding *whether* a tolerance should be adopted at all. If Congress intended the "to such extent" clause as nothing more than a limitation on the tolerance level set by the agency, as respondents contend, then logic would have dictated that it should have been placed in the final sentence of Section 406 along with the factors that the agency is expressly directed to "take into account" in "determining the quantity of such added substance to be tolerated."

avert this result by partially abandoning the construction of Section 406 that they championed in the court of appeals. There, respondents argued that a food was adulterated if it contained any amount of a necessary or an unavoidable added contaminant and no tolerance was in effect (see Resp. Br. 23 n.5),[2] and the court of appeals agreed.[3] Respondents have now forsaken that argument and agree with our position that food containing such a substance is adulterated only if a tolerance is in effect and the food contains that contaminant in an amount exceeding the tolerance. Respondents insist (Br. 20-22) that their new reading of Section 406 does not render Section 402 (a)(1) superfluous, because it can function as a transitional device until a tolerance has been adopted. However, respondents' argument suffers from much the same flaw as the court of appeals' reading of Section 406.

The only material difference between the interpretation of Section 406 that was adopted by the court of appeals and the one that is now offered by respondents is simply a matter of timing. Whereas the court of appeals' construction of Section 406 renders Section 402(a)(1) superfluous today, respondents' construction of Section 406 renders Section 402(a)(1) super-

[2] See also Plaintiffs-Appellants C.A. Br. 14, 19, 21; Plaintiffs-Appellants C.A. Reply Br. 3-4.

[3] Although they now agree with our construction of Section 406 on this point, respondents assert (Br. 23) that the court of appeals did not conclude that the absence of a tolerance automatically renders a food adulterated if it contains any quantity of a necessary or an unavoidable added contaminant. However, the court of appeals' opinion shows that respondents are wrong. See, *e.g.*, Pet. App. 7a ("[s]ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce"); *id.* at 4a, 15a.

fluous at some unknown day in the future. Respondents admit (Br. 12-13, 21-22) that, once the FDA adopts tolerances for necessary or unavoidable added contaminants, Section 402(a)(1) will have no role to play in their regulation. There is no evidence, however, that Congress intended the general adulteration standard in Section 402(a)(1) to be replaced by tolerances in every case or, in general, to have a half-life as respondents claim. Respondents' construction of the Act should therefore be rejected.

There was also no reason for Congress to have intended Section 402(a)(1) to function as a transitional provision. Congress has historically included transitional provisions in the FDCA only when it has enacted amendments providing that regulated articles may not be marketed in interstate commerce without a license from the FDA. For example, Congress added a transitional provision to the Color Additives Amendment of 1960, Pub. L. No. 86-618, § 203, 74 Stat. 404-407, because the amendment prohibited the use of color additives in food in the absence of a license. A transitional mechanism was therefore necessary to allow food containing previously used additives to be marketed until a food producer had the opportunity to obtain a license for the additive. But, as we have shown (Pet. Br. 20-23, 34-35) and as respondents now agree (Br. 22-23), a food containing an added contaminant (such as aflatoxin) is *not* adulterated if there is no tolerance in effect, *i.e.*, if there is no "license." That food can be marketed before a tolerance is adopted. Thus, it would have been pointless for Congress to have included a transitional provision for added food contaminants in the FDCA. Put another way, because Section 406 is not a licensing provision, it makes no sense to treat Section 402(a)(1) as a transitional provision.

To be sure, the FDA could rely on Section 402(a)(1) as a transitional device (albeit with the practical difficulties noted below) if the judgment below were affirmed. The relevant question, however, is not whether Section 402(a)(1) *could* serve this function, but is whether it was *intended to* or *must* fill *only* that function. Nothing in its text or legislative history suggests that it should be so limited. Furthermore, limiting the usefulness of Section 402(a)(1) in the manner that respondents suggest is inconsistent with this Court's decision in *Flemming* v. *Florida Citrus Exhange, supra,* which recognized that Congress intended to allow the FDA to rely on Section 402(a)(1) to enforce the food adulteration provisions of the FDCA on a case-by-case basis. See 358 U.S. at 166; Pet. Br. 34-35. Finally, as we pointed out in our opening brief (at 25), treating Section 402(a)(1) as a transitional provision will lead to considerable practical difficulties in the enforcement of the FDCA because Sections 406 and 402(a)(1) do not define the length of any transitional period or specify any factors for the courts to consider in deciding when it will expire. Respondents have failed to explain why their new reading of Section 406 will not simply invite needless litigation over this issue.[4]

b. In relying on the dictionary definition of the term "shall," respondents forget that Congress drafted the FDCA to function "as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943). Here, the legislative history of the FDCA clearly shows that Congress and the FDA both construed Section 406 as granting the agency the authority to set tolerances, not as requiring the agency to do so.

First, the original version of the FDCA (S. 1944, 73d Cong., 1st Sess. § 10(a) (1933)), which was drafted by the agency, also contained the verb "shall" that is found in the current version of Section 406. During the hearing on the bill, Walter Campbell, Chief of the FDA, repeatedly stated that the agency drafted this provision to supplement its enforcement authority under existing law by obtaining the discretionary authority to adopt

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[4] In fact, litigation over this question has already begun. In *National Wildlife Federation* v. *Bowen,* petition for review, No. 85-3943 (6th Cir. filed Nov. 11, 1985), the National Wildlife Federation, relying solely on the court of appeals' decision in this case, has asked the court of appeals to order the FDA to set a tolerance for dioxin in fish and other classes of food. If the court of appeals' decision here is upheld, it is reasonable to expect a spate of litigation along this line in which parties who are disappointed by the agency's failure to adopt a tolerance will claim that the FDA is required to issue one under Section 406 whenever it is asked to do so.

tolerances. Pet. Br. 28 & n.24.[5] Senator Copeland, whose views, as sponsor of that bill, offer an authoritative guide to its meaning (see *Grove City College* v. *Bell*, 465 U.S. 555, 567 (1984)), also read this section as empowering, not requiring, the FDA to establish tolerances. Pet. Br. 29. Plainly, neither of the principal architects of the bill believed that the dictionary meaning of the term "shall" was of any significance.

Congress also shared the agency's interpretation. The various bills considered as replacements for the Federal Food and Drugs Act of 1906, 21 U.S.C. (1928 ed.) 1 *et seq.*, used the terms "shall" and "is authorized to" interchangeably, but every committee report stated that the FDA would be authorized to set tolerances, regardless of the actual terms used by these bills. Pet. Br. 29-30 & nn.29-31. And at no time during the five-year period that the FDCA was under consideration did anyone suggest that the FDA should be required to adopt tolerances. Given this clear, oft-stated, and unwavering expression of Congress's and the agency's intent, their understanding of the term "shall," not Webster's, is dispositive.[6]

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[5] Respondents' quotation (Br. 27) from FDA Chief Campbell's testimony at the Senate committee hearing is seriously misleading. The eight words quoted by respondents come from his exchange with Senator Copeland in which he explained that the FDA sought the authority to adopt pesticide tolerances because they were the primary menace to public health. *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 25-26 (1933) [hereinafter cited as *1933 S. 1944 Hearings*]. Read as a whole, Campbell's testimony shows that he read Section 10(a) of S. 1944 as granting the agency discretionary authority to set tolerances. *1933 S. 1944 Hearings* 18-26, 80-81; Pet. Br. 28 & nn.24-25.

[6] Respondents find it "iron[ic]" (Br. 25) that, given the FDA's oft-stated request to be granted the authority to adopt tolerances, the agency has infrequently relied upon Section 406 since it was enacted. Respondents suggest (Br. 25) that the FDA has declined to adopt tolerances simply to "lessen the burdens" that the tolerance-setting process would impose on the agency. We agree with respondents that the tolerance setting process is quite burdensome (Pet. Br. 6-7, 45-47), but respondents err in suggesting that the agency has refused to carry out an express congressional directive simply to avoid the burden of formal rulemaking. The FDA has long found that case-by-case litigation fully protects the public health, and respondents do not claim that the agency's historic regulatory practice has jeopardized the public health in any respect. Moreover, history shows that respondents' criticism is unfounded

c. Equally important, however, is that respondents' account of the provenance of the term "shall" is *Hamlet* without the Prince of Denmark. Respondents have failed to offer any reasoned explanation why Congress would have sought to deprive the FDA of the discretion to select between the alternative methods of enforcing the food adulteration provisions set forth in Sections 402(a)(1) and 406 by requiring the FDA to adopt tolerances. Respondents do not suggest that Congress found that the FDA had inadequately enforced the adulteration provisions of the 1906 Act or that exclusive reliance on tolerances was the preferred way to protect the public health. The legislative history of the FDCA also discloses no criticism or finding of this type. Pet. Br. 30-31. In fact, the only criticisms of the FDA were voiced by the apple industry, which feared that the FDA would be too aggressive in its efforts to enforce the Act. Pet. Br. 31-32. And Congress incorporated into the FDCA the section in the 1906 Act that empowered the FDA to act on a case-by-case basis (see *Flemming*, 358 U.S. at 161; Pet. Br. 34-35), which shows that Congress did not forbid this regulatory approach.

Instead, respondents argue that Congress required the FDA to adopt tolerances in order to ensure "public participation" in the enforcement process. Br. (i), 2, 8, 14, 15, 35, 38. However, respondents' repeated references to Congress's asserted intent are not supported by a single reference to the legislative history of the Act. In fact, that history plainly shows that the administrative procedures found in Section 701(e) were added at the request of the apple industry to ensure that food producers, not consumers, would be able to participate in the tolerance-setting process. Moreover, these procedures were adopted not

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for another reason as well. Section 406 was adopted primarily to deal with the problem of pesticide residues in foods (Pet. Br. 17-18 n.14, 27 & n.21, 31-33) and, after a period during World War II, when the FDA's resources were diverted to other matters, the FDA adopted a tolerance for fluorine in 1944 (*id.* at 46 n.46). Once the Act of July 22, 1954 (the Pesticide Chemicals Amendment of 1954), 21 U.S.C. 346a, was adopted, there was no need to resort to Section 406 to adopt tolerances for pesticides. Most unavoidable added contaminants, such as aflatoxin, were not discovered until the 1960's. Pet. Br. 47-48 n.49. Respondents' criticism thus overlooks the historical context of the FDA's use of tolerances.

to require the FDA to set tolerances, but simply to ensure that the apple industry would be able to participate if the FDA decided to do so. Pet. Br. 31-34. Respondents' failure to explain why Congress would have intended to restrict the FDA's enforcement discretion is powerful evidence that Congress had no such intent in the first place. Indeed, because there is no evidence that Congress intended to restrict the FDA's discretion to enforce tolerances once they have been adopted (cf. *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985), slip op. 13-14), respondents' contention that Congress was concerned with public participation in the enforcement process is dubious on its face. And to the extent that respondents' construction of Section 406 is an attempt to place a contemporary gloss on a 1938 statute, their argument should be presented to Congress, not to this Court. See *Potomac Electric Power Co.* v. *Director, OWCP*, 449 U.S. 268, 280 (1980).[7]

2. Respondents also argue (Br. 26-31) that the legislative history of the FDCA is consistent with their construction of the text of Section 406. Respondents rely almost exclusively on two aspects of that history: (a) the fact that the House replaced the phrase "is authorized to" in the final Senate version of the FDCA with the term "shall," and (b) the fact that the House made the identical substitution in four other sections of the Senate bill. Neither argument has merit.

a. The House amendment to Section 406 is not significant in this case because the House Report and the floor debate show that the House intended Section 406 to authorize, not require, the FDA to establish tolerances. The House Report expressly stated that Section 406 "authorized" the FDA to adopt tolerances (H.R. Rep. 2139, 75th Cong., 3d Sess. 6 (1938)), and the explanatory remarks made during the floor debate on the House amendment by supporters and opponents of the amend-

[7] Section 701(e) does provide that the issuance, amendment, or repeal of a tolerance can be initiated by a proposal offered by the FDA or by a petition, "showing reasonable grounds therefor," filed by any interested person with the FDA. However, respondents never petitioned the FDA to set a tolerance for aflatoxin in corn or in any other food.

ment alike make the same point (Pet. Br. 33 & n. 35).[8] To be sure, the House Report does not explain why the House decided to modify the verb in the Senate bill. But respondents err in claiming that "[a]ll that is known" is that the House modified the Senate bill (Br. 28); the House Report and the floor debate demonstrate that the House did not intend its amendment to have a substantive effect. Thus, by itself the fact that the House modified the Senate version of Section 406 is of no consequence in this case.

Respondents attempt to explain away these direct and unequivocal statements of contrary congressional intent by contending (Br. 29) that they are "consistent with respondents' interpretation and the literal language of the statute." However, respondents are mistaken. Their argument (Br. 29) that "the

[8] The following excerpt from the House debate is illustrative (83 Cong. Rec. 7774 (1938) (emphasis added)):

> Mr. LEA: * * * The addition of poison to foods is prohibited except where such addition is necessary or cannot be avoided; and in such cases tolerances are provided limiting the amount of added poison to the extent necessary to safeguard the public health.
>
> At this point I call attention to the question discussed a while ago as [to] spray residue on fruit. *This bill provides that the Secretary of Agriculture shall have authority after proper hearing to prescribe the extent of spray residue that shall be permissible.* Then the regulation is enforceable. There is nothing in this bill that fails to protect the public health against spray residue. *In the present law there is no such authority in the Secretary of Agriculture. The only method of prosecuting in connection with that condition at the present time is to treat spray residue as an adulteration.*
>
> * * * * *
>
> Mr. SIROVICH: Is there anything in this measure which would compel the Government of the United States to insist upon the washing off of the toxic residue that may be found upon fruits and vegetables?
>
> Mr. LEA: The only way of handling that situation at the present time is for the Secretary to say, in effect, that if he finds more than a certain amount of spray residue, he will prosecute criminally for adulteration. *There is no authority by which he can legally adopt regulations. He must resort to the criminal procedure for adulteration. If enacted, this bill would give him the right after proper hearings to adopt regulations prescribing limits.* Then a court review would be permitted, and if the interested parties claimed the regulation was invalid, they would have the right to go into court and have that question considered.

principal focus of attention by everyone, including the FDA, was in creating this new [tolerance-setting] authority" in Section 406 is unsupported by anything in the legislative history. As we have explained in detail (Pet. Br. 28-34), Section 701 was the only subject of controversy (or even debate), not Section 406. From the outset, Congress acceded to the FDA's request that it be empowered to adopt tolerances as an additional enforcement tool to be used in the agency's discretion; the only controversy stemmed from the procedures that the agency proposed to adopt tolerances, not from its request for the discretionary authority to do so.[9]

Respondents' analysis of the legislative history is also premised on a misconception of the differences between action levels and tolerances. Respondents repeatedly assert that action levels are the same as tolerances.[10] Respondents then conclude (Br. 29-30) that, by requiring the FDA to follow the procedures set forth in Section 701(e) to set a tolerance, Congress prohibited the agency from relying on action levels to regulate the presence in food of any added contaminant for which the FDA could adopt a tolerance. However, respondents' premise is seriously flawed.

As we have explained (Pet. Br. 3, 5-6, 27-28), the FDA's action levels are, and have always been, informal and internal prosecutorial guidelines.[11] Contrary to respondents' assertions,

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[9] Indeed, respondents' analysis of the legislative history is self-defeating in this regard. If Section 406 truly were the "principal focus of attention," the House Report and the floor debate would take on heightened importance.

[10] For instance, respondents state that " 'action levels' have the same legal effect as a regulation issued under section 701(e) [*i.e.*, a tolerance]" (Br. 2), that a "tolerance operates like a license for food producers" (Br. 7), that action levels and tolerances "confer[] precisely the same benefits on food producers" (Br. 7), that "an action level binds the agency from proceeding against food producers" (Br. 12), that "action levels * * * authorize added poisonous and deleterious substances in food" (Br. 25); and that FDA's pre-1938 action levels, which the FDA termed, for want of a better name, "administrative tolerances" (*1933 S. 1944 Hearings* 22 (FDA Chief Campbell)), "amounted to a license to market foods as long as the contaminants were below the tolerance level" (Br. 27).

[11] Respondents also insist (Br. 5) that food containing any amount of aflatoxin is adulterated because there is no known safe level of aflatoxin contamination. However, that claim is both legally and factually erroneous. As a legal matter, since there is no tolerance in effect for aflatoxin, the FDA must prove under Section 402(a)(1) that food containing aflatoxin may "render [the food] injurious to health" (21 U.S.C. 342(a)(1)). See *Fleming*, 358 U.S. at 161; *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914); Pet. Br. 4. The issue is not whether the substance itself (or the food) has been proven to be safe. As a factual matter, the evidence shows that food must contain 20 parts per billion (ppb) of aflatoxin in order for it to present any reasonable possibility of harm. J.A. 188, 193, 194, 225. For certain uses, moreover, corn must contain more than 100 ppb aflatoxin before it may become injurious to health. Pet. Br. 9-10 n.10. The FDA's current 20 ppb action level for aflatoxin therefore does not represent any largesse on the part of the agency, as respondents suggest (Br. 7, 9, 12, 32). Rather, the action level represents the level of contamination at which the FDA has the evidence of a reasonable possibility of injury that is necessary to prove adulteration under Section 402(a)(1). Pet. Br. 8-9.

action levels do not "authorize" food producers to do anything.[12] Nor does a violation of an action level render a food per se adulterated; on the contrary, the FDA must prove in court in each case that a particular contaminated food may be injurious to health. By contrast, tolerances have the force and effect of law. Once a tolerance is set, food containing a contaminant in an amount below the tolerance level is not adulterated, but a violation of a tolerance does render a food per se adulterated. Thus, given the critical differences between these alternative enforcement mechanisms, the fact that Congress required the FDA to follow specific procedures to adopt a tolerance does not, by negative implication, suggest that Con-

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[12] Respondents also erroneously claim (Br. 7) that, so long as the level of a contaminant does not exceed the amount that is "authorized" by an action level, "food producers receive full protection from FDA enforcement actions." Action levels are similar to FDA advisory opinions (see 21 C.F.R. 10.85) or guidelines (see 21 C.F.R. 10.90), and the FDA's regulations explicitly state that, in unusual situations involving an immediate and significant danger to public health, the agency may take appropriate civil enforcement action contrary to an advisory opinion (21 C.F.R. 10.85(f)) or a guideline (21 C.F.R. 10.90(b)(3)) before it is revoked or amended. Cf. *McIlwain* v. *Hayes*, 530 F. Supp. 973, 977-978 n.8 (D.D.C. 1981), aff'd, 690 F.2d 1041 (D.C. Cir. 1982) (FDA not bound in court by advisory opinions). Accordingly, if the FDA were to conclude that its 20 ppb action level for aflatoxin presented a danger to the public health, the agency has the authority to take immediate action before that action level is modified.

gress also prohibited the agency from relying on action levels. Respondents' argument falls with its premise.

b. Respondents also rely (Br. 19-20, 30) on the fact that the House replaced the term "is authorized to" in the Senate bill with the verb "shall" in four other places in the FDCA, Sections 401, 406(b), 501(b), and 604. But here, too, the House Report shows that these amendments were not substantive, because it spoke in terms of granting the FDA the "authority" to act. H.R. Rep. 2139, *supra*, at 5, 6, 9.[13] Indeed, respondents concede as much (Br. 30). In fact, this Court read one of these sections in precisely that way in *Federal Security Adm'r* v. *Quaker Oats Co.*, 318 U.S. 218, 230 (1943) (emphasis added; citation omitted), stating that "it was the purpose [of Section 401] to *authorize* the Administrator to promulgate definitions and standards of identity 'under which the integrity of food products can be effectively maintained.' " See also *id.* at 232 (emphasis added) ("[t]he statute accomplished that purpose [of providing consumers with information] by *authorizing* the Administrator to adopt a definition of identity * * *").[14] Accordingly, these amendments prove our point, not respondents', because they demonstrate that the House saw no difference between the terms "is authorized to" and "shall."

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[13] *Id.* at 5 ("Section 401 provides much needed authority for the establishment of definitions and standards of identity and reasonable standards of quality and fill of container for food"; noting that the bill "authoriz[es] the establishment of definitions and standards of identity"); *id.* at 6 ("Subsection (b) of this section [*i.e.*, 406] specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe"); *id.* at 9 ("Section 604 authorizes certification of coal-tar colors for cosmetics and is similar to sections on this subject provided with respect to foods and drugs"). The House Report does not use the term "authorize" in connection with Section 501(b), 21 U.S.C. 351(b) (see H.R. Rep. 2139, *supra*, at 6-7), but the FDA has also never construed this subsection as being mandatory.

[14] Respondents suggest (Br. 19-20) that the Court's decision in *Quaker Oats* construed Section 401 as requiring the FDA to adopt food identification standards, but the opinion will not bear that reading. The question in *Quaker Oats* was whether certain such standards were supported by substantial evidence, and the passages from the Court's opinion that are quoted by respondents came during the course of the Court's discussion of the factors that the agency must take into account when it adopts a food identity standard. See 318 U.S. at 227-228. Properly read, these passages mean only that the FDA must consider the statutory factors when it decides to adopt food identity standards. In addition, the passages quoted above in the text show that the Court did not construe Section 401 as respondents suggest.

3. We explained in our opening brief (at 39-43) that the FDA brought its interpretation of Section 406 to Congress's attention on three separate occasions when Congress considered revisions to the Act—in 1954, when Congress adopted the Pesticide Chemicals Amendment, 21 U.S.C. 346a; in 1958, when Congress adopted the Food Additives Amendment, Pub. L. No. 85-929, 72 Stat. 1784 *et seq.*; and in 1960, when Congress adopted the Color Additive Amendments, Pub. L. No. 86-618, 74 Stat. 397 *et seq.* At no time did Congress criticize the FDA's regulatory practice or require the agency to alter it, and Congress relied on the FDA's construction in adopting the 1954 amendment. Whatever doubts there may be in other contexts of the strength of subsequent legislative history such as this, here these amendments show that the FDA has correctly discerned Congress's intent. See *Bob Jones University* v. *United States*, 461 U.S. 574, 601-602 (1983); *United States* v. *Rutherford*, 442 U.S. 544, 554 & n.10 (1979).[15]

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[15] Respondents' argument (Br. 24) that the FDA's construction of Section 406 is neither longstanding nor consistent borders on the frivolous. The FDA first stated its position in 1933 when the agency drafted and submitted to Congress the bill that ultimately became the FDCA and when FDA Chief Walter Campbell testified before a congressional committee (Pet. Br. 28-29); the FDA publicly announced its position in trade correspondence issued in the 1940's shortly after the FDCA was adopted (*id.* at 17 n.14, 37 n.38); the FDA expressly brought its position to Congress's attention on three occasions between 1953 and 1960 (*id.* at 40 n.41, 42 n.42); and the FDA's position is reflected in its current regulations, which were adopted in the 1970's (*id.* at 37-38). That the FDA did not set tolerances for food contaminants once the FDCA went into effect (*id.* at 36) also provides a " 'contemporaneous construction of a statute by the men charged with the responsibility of setting its machinery in motion, of making the parts work efficiently and smoothly while they are yet untried and new.' " *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965) (citation omitted). Finally, since 1938 the FDA has regulated the presence of added contaminants in food primarily, albeit not exclusively, by relying on action levels in case-by-case litigation under Section 402(a)(1). Pet. Br. 3, 5-8, 43 & n.43.

Ignoring the last two occasions, respondents contend (Br. 35-38) that the legislative history of the Pesticide Chemicals Amendment of 1954 shows that Congress disapproved of the FDA's reliance on action levels. However, respondents' arguments are either beside the point or misconstrue that amendment.

a. Respondents' first argument (Br. 37) is that it would have been unnecessary for Congress to adopt a special tolerance-setting procedure for pesticides if the FDA could have regulated these substances by relying on informal action levels. However, here, too, respondents' argument ignores the critical differences between action levels and tolerances. The failure to comply with a pre-1954 pesticide action level did not constitute a per se violation of the FDCA any more than the failure to comply with the action level currently in force for aflatoxin amounts to a per se violation of the Act today. Only the failure to comply with a tolerance has that effect. Congress's decision in 1954 to adopt a streamlined procedure to set pesticide tolerances thus hardly signifies its disapproval of the FDA's prior reliance on action levels for pesticides, much less the agency's current reliance on action levels to regulate added contaminants that were not affected by that amendment.

b. Respondents similarly argue (Br. 37-38) that Congress disapproved the FDA's use of action levels because Congress, by enacting Section 408(j), 21 U.S.C. 346a(j), as part of the 1954 amendment, authorized the FDA to set a "temporary tolerance" for pesticides that are used on an experimental basis. It was unnecessary for Congress to do so, respondents claim, if the FDA could have achieved the same result by relying on action levels.

Here, too, respondents have confused action levels with tolerances, and their argument must be rejected for that reason alone. But respondents' argument is flawed for another reason as well. Congress adopted Section 408(j) in the 1954 Amendment because Sections 408(a) and 402(a)(2)(C) of that Amendment, 21 U.S.C. 346a(a) and 342(a)(2)(C), unlike Sections 406 and 402(a)(2)(A) of the FDCA, 21 U.S.C. 346 and 342(a)(2)(A), prohibit the addition to food of a pesticide unless (i) a pesticide tolerance is already in effect and the amount of that pesticide in the food is within the tolerance limits, or (ii) the pesticide has

been exempted from this requirement. In other words, because a pesticide cannot be used in food in the absence of a tolerance or an exemption, it was necessary for Congress to adopt Section 408(j) in order to authorize the FDA to set temporary tolerances providing for the experimental use of pesticides. Therefore, Congress did not adopt Section 408(j) to prohibit the FDA from relying on action levels or because Congress disapproved that practice. Rather, Congress adopted the temporary tolerance provision of Section 408(j) for reasons that are peculiar to the new system for regulating pesticides.

c. Finally, relying on the fact that Congress responded to the specific problems presented by pesticides by carving out a separate procedure for their regulation and not by changing the general scheme for regulating added contaminants under Section 406, respondents challenge (Br. 38) our argument that Congress was critical of the formal rulemaking requirements of Section 701(e), 21 U.S.C. 371(e), that are necessary to set tolerances. However, our argument was based upon (Pet. Br. 41-42, 46-47) the clear and unequivocal criticisms stated in the Senate and House Reports of the then-existing tolerance-setting procedures in Section 701(e). These criticisms speak for themselves and provide a complete answer to respondents' argument. Respondents concede (Br. 37) that the 1954 Amendment was enacted to establish a less time-consuming and less cumbersome tolerance-setting procedure for pesticides than the one prescribed by Section 701(e). That Congress did not also alter the procedural requirements imposed by Section 701(e) for the added substances that remained within the scope of Section 406 is beside the point, which is that Congress endorsed the FDA's construction and implementation of Sections 406 and 402(a)(1) when it enacted the 1954 Amendment. Only if the FDA wished to establish tolerances under Section 406 by informal rulemaking would the agency have needed to persuade Congress to amend the procedural requirements of Section 701(e) insofar as they apply to Section 406, or to amend Section 406 to exclude from its scope added contaminants other than pesticides. Respondents' argument is simply not responsive to our point.

4. Finally, respondents argue (Br. 31-35) that the FDA has overstated the adverse effects of the court of appeals' decision. Respondents discount (Br. 32-33) the risk that tolerances will hamper the agency's ability to respond to new toxicological data or changes in manufacturing practices by asserting that the FDA has never lowered its action levels in response to an emergency and by arguing that the formal rulemaking requirements will not retard the agency's ability to respond to an emergency should one develop. However, respondents' assertions are factually wrong, as the FDA's experience with polybrominated and polychlorinated biphenyl contamination reveals.[16] More importantly, the agency can hardly be criticized for its unwillingness to risk the public health by assuming that no emergencies will occur. Finally, any interpretation of the FDCA that requires the agency to take risks of this type is inconsistent with the principle that the Act should be liberally construed to protect the public health. See *United States* v. *An Article of Drug * * * Bacto Unidisk*, 394 U.S. 784, 798 (1969).

Respondents maintain (Br. 34) that their construction of the Act will not burden the FDA. For instance, they suggest that FDA can lessen the burden of formal rulemaking by relying on the summary judgment procedures upheld in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), in the

[16] In May and June 1974, following the discovery of the blending of polybrominated biphenyls (PBBs) and animal feed that resulted in the contamination of Michigan dairy cattle, the FDA established action levels of 1.0 parts per million (ppm) for PBBs in milk and meat fat, 0.1 ppm for PPBs in eggs, and 0.3 ppm for PBBs in animal feed. In November 1974, following a more detailed review of PBB toxicity, including toxicity studies conducted by its Bureau of Foods, as well as advances in the analytical methods for detecting the presence of PBBs in foods and feeds, the FDA lowered the action levels to 0.3 ppm for PBBs in milk and meat fat, 0.05 ppm for PBBs in eggs, and 0.05 ppm for PBBs in feed. See *Toxic Substances: Hearings on Polybrominated Biphenyl Contamination in Michigan Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation*, 95th Cong., 1st Sess. Pt. 2, at 954, 968-971, 1007-1011, 1028, 1046, 1057, 1417 (1977). Had a tolerance been in effect for PBBs in foods and feeds, the FDA would not have been able to respond nearly as quickly to the new toxicological data, as demonstrated by the agency's experience in attempting to lower the tolerance for polychlorinated biphenyls in food (Pet. Br. 45 n.45).

context of new drug applications. But, as we have explained (Pet. Br. 46-47 n.47), there is no reason to presume that such a procedure will substantially reduce the burdens imposed by formal rulemaking, or will not lead to unnecessary litigation over this question. Respondents also argue (Br. 35) that setting tolerances is a more efficient way to protect the public health than case-by-case litigation. But the question of how best to regulate contaminants such as aflatoxin involves precisely the type of scientific and policy judgments that Congress has entrusted the FDA to make. See *Chaney*, slip op. 10; *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411, 413 (1958) ("the Commission alone is empowered to develop that enforcement policy best calculated to achieve the ends contemplated by Congress and to allocate its available funds and personnel in such a way as to exercise its policy efficiently and economically").

At bottom, respondents misconstrue the significance of our reliance on these so-called "policy considerations" (Br. 31). We do not contend that the FDA may dispense with the burden of setting tolerances through formal rulemaking requirements if Congress in fact required the agency to regulate in that manner. Rather, our submission is that the agency has long concluded that in many circumstances the costs of adopting tolerances outweigh their benefits, there is no evidence that Congress disagrees with the agency, and, accordingly, there is no good reason to construe the FDCA in a manner that requires the agency to abandon its longstanding and successful regulatory practice.

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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